DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 6 2002

9546 '02 MAY -8 P1:34

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Laverne M. Charpentier
1303 Oakburn Drive
Walnut, CA 91789

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 00N-1527

Dear Ms. Charpentier:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The FDA bases this proposal on a finding that you were convicted of one count of conspiring to make false statements in matters within the jurisdiction of a government agency, a Federal felony offense under 18 U.S.C. sections 371 and 1001, and that your conduct undermined the process for the regulation of drugs. This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Debarment

On October 21, 1997, the United States District Court for the Central District of California accepted your plea of guilty to one count of conspiring to make false statements in matters within the jurisdiction of a government agency under 18 U.S.C. sections 371 and 1001. The underlying facts supporting this felony conviction are as follows:

At the time of the wrongful conduct, you were employed by American Pharmaceutical Research, Inc., formerly known as Southern California Research Institute (collectively SCRI), as a drug study coordinator. SCRI was a private company retained by drug manufacturers to conduct clinical studies of new pharmaceutical products to be submitted to FDA in support of approval of the drug products. Dr. Robert A. Fiddes was the owner and president of SCRI and the principal investigator for all drug research conducted at SCRI.

In your capacity as a drug study coordinator at SCRI, you participated in the conduct of numerous clinical studies to test the safety and effectiveness of investigational new drugs (INDs) on human subjects. Beginning on a date unknown and continuing through at least December 1, 1996, you, at the direction of Dr. Fiddes, and at times in conjunction with other study coordinators, routinely falsified data on the studies. You admitted that you, among other things: falsely reported that certain subjects participated in clinical trials when in fact, they had not; substituted samples and data from qualifying subjects for nonqualifying subjects; and enrolled

nonexistent and nonqualifying subjects in the clinical studies and falsified data for those nonexistent and nonqualifying subjects. You knew that the fabricated data and information would be provided to the drug sponsors who, in turn, would submit such data and information to FDA in support of their new drug applications for their drug products.

FDA's Finding

Section 306(b)(2)(B)(i)(II) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits the FDA to debar an individual if it finds that the individual has been convicted of a felony under Federal law for conspiracy to commit a criminal offense relating to the development or approval, including the process for the development or approval, of any drug product, or otherwise relating to the regulation of drug products, under the Act and that the conduct undermines the process for the regulation of drugs. Your felony conviction under 18 U.S.C. sections 371 and 1001 was for conspiring to defraud FDA by falsifying important data in studies used by the Agency to determine whether new drugs should be approved, an offense relating to the development or approval of any drug product. This conduct undermines the process for the regulation of drugs. Accordingly, the Agency finds that you are eligible for permissive debarment.

Under section 306(l)(2) of the Act, permissive debarment may be applied when an individual is convicted within the 5 years preceding this notice. You were convicted on October 21, 1997, less than 5 years ago. The Agency may debar you for up to 5 years for each offense, and can determine whether the debarment period for multiple offenses shall run concurrently or consecutively (306(c)(2)(A) of the Act) (21 U.S.C. 335a(c)(2)(A)).

Section 306(c)(3) of the Act provides six factors for consideration in determining the appropriateness of and the period of permissive debarment for a person (21 U.S.C. 335a(c)(3)). These are as follows:

> (A) the nature and seriousness of any offense involved,
>
> (B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,
>
> (C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this Act of under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

The Agency considers that four of these factors are applicable for consideration:

1. The nature and seriousness of the offense involved (Factor A)

You were convicted of one count of conspiring to make false statements to a government agency, the FDA, based on your participation in falsifying data and information in clinical studies for use by FDA in determining the safety and effectiveness of drug products. Your illegal conduct involved numerous drug products indicated for a variety of conditions.

The Agency finds that your conduct undermined the integrity of the drug approval and regulatory process because FDA's regulatory decision on whether or not to grant or withhold approval of the drugs was based on information that you falsified on the studies and submitted to the drug sponsors in required reports. Accordingly, the Agency will consider the nature and seriousness of the conduct underlying your conviction as an unfavorable factor.

Furthermore, some of the drugs for which you submitted false data, for example, Dilacor and Salmeterol, are indicated for serious or life-threatening conditions. Dilacor is indicated for the treatment of hypertension and for the management of chronic stable angina. Salmeterol is indicated for the maintenance treatment of asthma and in the prevention of bronchospasm (*2002 Physicians Desk Reference*). Accordingly, the Agency will consider your conduct an extremely unfavorable factor because your actions potentially undermined the safety or effectiveness of drugs used for life-threatening or serious conditions.

2. The nature and extent of management participation in any offense involved whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense (Factor B)

You participated in the planning of, directed, or initiated the conduct underlying your conviction. You admitted that you, together with other study coordinators and Dr. Fiddes, routinely and

deliberately failed to conduct clinical studies in accordance with study protocols, fabricated data on the studies to conceal such illegal conduct, and submitted the fraudulent data to sponsors of the drugs in required reports. Therefore, the Agency considers the nature and extent of your participation as an unfavorable factor.

3. The nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health (Factor C)

You did not report drug-related violations nor did you take action to correct the violations, although you knew the actions were violative of the law. You admitted that you were aware of, but routinely violated, the regulations governing the conduct of clinical studies involving INDs. Specifically, you admitted that you, under the direction of Dr. Fiddes and at times together with other SCRI staff, allowed your maiden name and personal data to be used to create false documentation indicating that a "Laverne M. Chocek" was participating in a study on a drug product known as Triphasic Pill; instructed another study coordinator to use running water instead of the subject's own urine to falsely create qualifying flow meter data to enroll otherwise nonqualifying subjects in a study on drug products known as Alpha Blocker/SB216469-S and Epristeride; assisted Dr. Fiddes in destroying x-ray film reports showing that certain subjects enrolled in a study on the drug product known as PHZ-136 did not have osteoarthritis of the knee as required by the study protocol; falsified study documentation to make it appear that more than 25 subjects participated in a study on Clotrimazole when only one subject participated in the study; allowed your daughter's name and personal data to be used to create documentation falsely indicating that she was fully participating in a study on Salmeterol; purchased microorganisms from an outside laboratory and used the microorganisms to qualify otherwise nonqualifying subjects in a study on Azithromycin; enrolled nonexistent subjects in a study on Dilacor and falsified Holter monitor data relating to heart rhythm measurements for certain subjects who did not participate in the study; enrolled otherwise nonqualifying subjects into drug studies by falsifying subjects' electrocardiogram results and by substituting subjects' blood with your own blood and the blood of other study coordinators at SCRI. You knew the drug sponsors of the drug products studied would submit the fraudulent data to FDA to support approval of new drug applications on the drugs.

Accordingly, the Agency considers the nature and extent of mitigation an extremely unfavorable factor, because the facts support the belief that you displayed a wanton disregard for the public health and the drug regulatory process.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration (Factor F)

The Agency is unaware of any prior convictions.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, the FDA proposes to issue an order under section 306(b)(2) of the Act debarring you from providing services in any capacity to a person that has an approved or pending drug product application for one period of 5 years. You were convicted of one count of conspiracy to make false statements to a government agency, a felony described in section 306(b)(2)(B)(i)(II) and (a)(2). Because you were convicted of one count, FDA has determined that you committed one offense. The Agency intends to implement the maximum debarment period for the offense based on the factors discussed above.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity for a hearing to show why you should not be debarred as proposed in this letter. If you decide to seek a hearing, you must file: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing, and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, notice of appearance and request for a hearing, information and analyses to justify a hearing, and determination of a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing on your debarment, and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, the Agency will not hold a hearing and will issue the debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact which precludes the order of debarment, the Commissioner of Food and Drugs will enter summary judgment against you, making findings and conclusions, and denying a hearing.

Laverne M. Charpentier

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates your debarment as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 00N-1527 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20857. You must file four copies of all submissions under this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.99).

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research